

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING  
PHARMACY, INC. PRODUCTS  
LIABILITY LITIGATION

MDL No. 2419

Dkt. No. 1:13-md-2419 (FDS)

THIS DOCUMENT RELATES TO:

All Actions

**PLAINTIFFS' STEERING COMMITTEE'S RESPONSE TO TENNESSEE  
DEFENDANTS' AND SAINT THOMAS ENTITY'S PROPOSALS  
REGARDING PROFILE FORM AND AUTHORIZATIONS**

The parties filed three separate proposals pursuant to Judge Boal's January 7, 2014 Order.<sup>1</sup> On January 24, 2014, counsel for Saint Thomas Outpatient Neurosurgical Center, LLC, Howell Allen Clinic, a Professional Corporation, John W. Culclasure, MD, Debra V. Schamberg, RN; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; and Kenneth Lister, MD, PC, (collectively, the "Tennessee Defendants") filed a proposal.<sup>2</sup> On the same day, counsel for Saint Thomas Health, Saint Thomas Hospital West f/k/a Saint Thomas Hospital, Saint Thomas Network (collectively, the "Saint Thomas Entity") filed their own proposal.<sup>3</sup> On January 27, 2014,<sup>4</sup> the Plaintiffs' Steering Committee ("PSC") filed its own proposal.<sup>5</sup> The PSC now files this response to the competing proposals offered by the Tennessee Defendants and the Saint Thomas Entity in an effort to clarify the differences between the competing proposals.

In developing its proposed Plaintiff Profile Form and authorizations, the PSC was cognizant of Judge Saylor's instruction that the form is meant to allow the parties to "make a

<sup>1</sup> Dkt. No. 748.

<sup>2</sup> Dkt. No. 807, the "Tennessee Def. Proposal."

<sup>3</sup> Dkt. No. 808, the "Saint Thomas Entities Proposal."

<sup>4</sup> The PSC had planned to submit this filing on Friday, January 24, 2014, but due to the nationwide disruption to the U.S. Court's CM/ECF system, the PSC was unable to do so, and as a result submitted this filing as soon as practicable the next business day.

<sup>5</sup> Dkt. No. 809.

meaningful analysis of a case for purposes of selecting potential ‘bellwether’ cases.’”<sup>6</sup> Indeed, bearing those instructions in mind, the PSC made vast, meaningful additions to its initial proposal of the PITWD Addendum and medical authorization and significant compromises in an attempt to reach agreement without court intervention. Alternatively, the defendants’ have failed to make any meaningful compromises despite Judge Saylor’s caution to exclude “marginally material” requests. The PSC maintains its proposed form and authorizations satisfy Judge Saylor’s goal given the intricacies of this MDL.

The Defendants acknowledge that the Court, in developing a profile form should be guided, and must be guided, by the unique nature of this MDL, but the Defendants’ fact sheet and authorization proposals appear to ignore this very same sentiment. Specifically, unlike in many MDL’s cited by the Defendants, the vast majority of cases in this MDL involve: 1) the administration of a single product (NECC’s MPA), 2) over a relatively short and identifiable period of time (a few months), and 3) that caused a specific and unique medical problem/outcome (fungal meningitis/infection).<sup>7</sup>

The Defendants submit numerous fact sheets used in other mass tort MDLs as support for their proposed fact sheets here. However, a review of those previously used fact sheets reflects that there were efforts to grapple with complex causation questions relating to whether a single drug product caused common health problems that frequently occur without exposure to the particular drug product at issue. For example, both the Tennessee Defendants and the Saint Thomas Entity submit the profile form used in the *Vioxx* products liability litigation in support of

<sup>6</sup> Dkt. No. 722 at P. 2-3.

<sup>7</sup> The Saint Thomas Entity filed with their proposal an article from the New England Journal of Medicine detailing the causal link between exposure to the NECC MPA and the onset of fungal meningitis symptoms, which is a tacit acknowledgement by the defendants that there is really no reasonable basis to dispute the causal link between the harms suffered and alleged by plaintiffs in this litigation and their exposure to an NECC product.

their proposed forms here.<sup>8</sup> The *Vioxx* MDL involved a drug that had been on the market for years, was taken by millions of people, and was alleged to cause a relatively ubiquitous medical problem: cardiovascular disease, stroke and symptoms of the same. In other words, the potential cases in that case involved a far more complex set of medical and causation issues impacting a far larger number of people over a significantly longer period of time, and, therefore, by definition, necessarily involved a far more diverse universe of plaintiffs and alternative medical causes than that involved here. In contrast, fungal meningitis is virtually unheard of and causation by contaminated NECC MPA cannot be seriously contested, as it is a signature disease.<sup>9</sup>

Yet, interestingly, the profile form used in the *Vioxx* litigation was only eleven pages and had four document requests, a far less invasive form than the one offered by both the Tennessee Defendants and the Saint Thomas Entity here. The same thing is true of many of the profile form sheets used as examples by both the Tennessee Defendants and the Saint Thomas Entity.<sup>10</sup>

In MDL 2428: *In Re: Fresenius Granuflo/Naturalyte Dialysate Products Liability Litigation*, (“*Granuflo* Litigation”), a relatively similar MDL to the one at bar and pending in this district, Judge Woodlock entered an approximately four page fact sheet that contained none of the employment history, medical history, education history, and family background information or the employment record, insurance record, worker’s compensation record, and/or tax record releases the PSC has voluntarily agreed to produce in this litigation.<sup>11</sup> And in the *Granuflo*

<sup>9</sup> As one court has phrased it, “[s]ignature diseases are those that are uniquely related to exposure to a certain substance and are rarely observed in individuals that are not exposed. See *Hurtado v. Pharma Co.*, 6 Misc. 3d 1010(A), 2005 WL 192351 at \*6 (N.Y. Sup. Ct. 2005).

<sup>10</sup> See e.g. *Propulsid* Fact Sheet, 12 pages of questions no document requests in case involving a drug that purportedly caused heart disease and other cardiovascular ailments (Dkt. No. 807-2 at P. 20); *Ethicon* Fact Sheet, 5 pages of questions and no document requests in case involving defects in transvaginal mesh product that caused numerous urinary, reproductive, and other vascular ailments (Dkt. No. 807-2 at P. 32).

Litigation, there are far more complex issues involved. For example, the actual manufacturer of the dialysate is an underlying issue and there are extensive medical causation questions to be explored to identify the actual cause of the cardiac arrest or stroke – both issues that are not present here, yet the profile form Plaintiffs have agreed to is double in size.

The purpose of the Plaintiff's Profile Form is to facilitate the selection of representative cases to be placed in a trial pool that will then go on to full discovery. To make those meaningful selections, Defendants simply do not need much of the information they are now insisting upon. For example, the following requests appear in both the Tennessee Defendant's and Saint Thomas Entity's proposal, but will likely provide no meaningful input on whether a given case is representative and merely appear to be a fishing expedition:

1. Whether a plaintiff has filed previous lawsuits on any issue;<sup>12</sup>
2. The plaintiff's drivers license number;<sup>13</sup>
3. Where the plaintiff lived in 2004;<sup>14</sup>
4. The plaintiff's spouse's occupation and date of birth;<sup>15</sup>
5. Whether a plaintiff's relative suffered from, among other requests: HIV/AIDS, neuropathy, thyroid problem, liver disease, hepatitis, kidney failure, depressions, cirrhosis;<sup>16</sup>
6. Plaintiff's alcohol use or illicit drug use;<sup>17</sup> and
7. Whether plaintiff has taken insulin, narcotic pain relievers, muscle relaxers, over the counter pain relievers at any time in the past ten years.<sup>18</sup>

This list is not meant to be exhaustive, but merely illustrative of the Defendants' proposed forms over breadth and undue burden of them. Put simply, Defendants do not need to

<sup>12</sup> Dkt. No. 807-1 at Request 14; Dkt. No. 808-1 at Request 15.

<sup>13</sup> Dkt. No. 807-1 at Request 19; Dkt. No. 808-1 at Request 19.

<sup>14</sup> Dkt. No. 807-1 at Request 20; Dkt. No. 808-1 at Request 22.

<sup>15</sup> Dkt. No. 807-1 at Request 23; Dkt. No. 808-1 at Request 26.

<sup>16</sup> Dkt. No. 807-1 at Request 26; Dkt. No. 808-1 at Request 29 and 30.

<sup>17</sup> Dkt. No. 807-1 at Request 42-43; Dkt. No. 808-1 at Request 49-50.

<sup>18</sup> Dkt. No. 807-1 at Request 46; Dkt. No. 808-1 at Request 53.

know whether a given plaintiff took Advil for a headache in September of 2004 to make meaningful selection of cases for potential bellwether trials.

The parties not only disagree on the types of questions that are appropriate, but the parties also disagree on the scope of certain requests for selection of potential bellwether cases, such disagreements include:

1. The period for which Plaintiff should disclose the following:
  - a. medical history (5 years v. 10 years)
  - b. employment history (6 years v. 10 years)
  - c. residency history (5 years v. 10 years).
2. Whether Plaintiffs must disclose in full detail their method and evaluation of lost earnings and earning capacity;
3. The scope of illnesses, unrelated to claims made in this action, Plaintiff must identify that he/she has been diagnosed with;
4. Whether Defendant is entitled to discovery over all applications for any disability and workers' compensation benefits regardless of time and whether an award was rendered.

It goes without saying that Defendants simply do not need to know if a plaintiff filed a claim for temporary disability benefits or a workers' compensation claim in 2005 to allow the Defendants to make meaningful selections on cases for potential bellwether trials. Such requests are unnecessarily broad and burdensome to plaintiffs who are already suffering, without much hope of true compensation for the level of injuries which they have sustained. Forcing plaintiffs into a fishing expedition at this stage in the litigation is entirely unnecessary and prejudicial. Surely the Defendants will get the discovery they need of potential bellwether plaintiffs once those cases are selected. Now is simply not the time to subject hundreds of plaintiffs to overly broad and burdensome discovery.

The PSC's proposed form, unlike the Defendants' proposals, appropriately balances the needs of the parties without imposing unnecessary and invasive questions bearing little to no relevance to the claims made in this action. Judge Saylor apparently agrees when, after the Defendants submitted substantially the same form as they offer now, he cautioned that such a proposed form may "sweep[] so broadly as to require the production of information that is of marginal materiality or relevance."<sup>19</sup>

Accordingly, the PSC urges the Court to adopt its proposed profile form and authorizations in lieu of those offered by the Tennessee Defendants and the Saint Thomas Entity.

Date: January 31, 2014

Respectfully submitted:

**/s/ Kristen Johnson Parker**

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<sup>19</sup> Dkt. No. 722 at P. 3.

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*Plaintiffs' Steering Committee*

CERTIFICATE OF SERVICE

I, Kristen Johnson Parker, hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Date: January 31, 2014

/s/ Kristen Johnson Parker  
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